K132167

MAY 0 2 2014

Section 5: 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21CFR, Section 807.92 (c).

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Date: **March 03, 2014**

Device Information:

Trade Name: *i*-CHROMA iFOB with *i*-CHROMA Reader
Common Name: *i*-CHROMA iFOB
Classification Name: Automated Occult Blood Analyzer
Class: II
Panel: Hematology
Product Code: OOX
Regulation: 21 CFR § 864.6550

Predicate Device: OC Auto Micro FOB Test and Polymedco OC Auto Micro 80 Analyzer
Predicate K Number: K041408

Device Description:

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples.

Intended Use(s):

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples. *i*-CHROMA iFOB is an *in vitro* diagnostic test used by laboratories and physician offices for routine physical examination when gastrointestinal bleeding may be suspected.

Indications for Use(s):

i-CHROMA iFOB is an *in vitro* diagnostic test used by laboratories and physician offices for routine physical examination when gastrointestinal bleeding may be suspected.

Components of *i*-CHROMA iFOB:

i-CHROMA iFOB consists of a 'Test Cartridge', an 'ID Chip' and a 'Sample Collection Tube' containing the 'Detection Buffer' and *i*-CHROMA Reader

- The test cartridge contains a test strip; on the nitrocellulose membrane of which, murine antibodies against human hemoglobin and rabbit immunoglobulin-G have been immobilized at the test line and the control line respectively. Each test cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed test cartridges are packed in a box which also contains an ID chip.

- The detection buffer contains fluorochrome-labeled anti-human hemoglobin antibodies, fluorochrome-labeled anti-rabbit immunoglobulin-G, bovine serum albumin (BSA) as a stabilizer, and sodium azide in phosphate buffered saline (PBS) as a preservative. Each sample collection tube contains 1 mL detection buffer. 25 pre-filled sample collection tubes are packed in a box which is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

- Additionally, 'Patient Packs' are provided along with the test cartridge box and also separately on demand.

  Each 'Patient Pack' contains following items:

  - 1 Patient Instructions Leaflet (for sampling instructions)
  - 1 Sample Collection Paper (for fixing onto the toilet bowl)
  - 1 Sample Sac (for enclosing the sample collection tube after sampling)
  - 1 Return Envelop (for submitting the sample collection tube to the laboratory/physician office for testing)

- *i*-CHROMA Reader is a fluorometer instrument which scans the sample-loaded *i*-CHROMA iFOB test cartridge and displays the test result. *i*-CHROMA Reader and *i*-CHROMA iFOB are compatible only with each other. *i*-CHROMA Reader is marketed/supplied separately on demand.

- The ID chip contains a memory device that contains encoded calibration data/information for the batch-to-batch (lot-to-lot) variation. With the ID chip inserted in the designated port, *i*-CHROMA Reader reads and utilizes the calibration data regarding the batch/lot under consideration and applies appropriate correction to the conversion formula while computing the test result.

_i_-CHROMA iFOB Test Cartridge:

_i_-CHROMA iFOB Test Cartridge is composed of a test strip enclosed in a disposable plastic housing.

The components of the test strip are:

- An antibody-immobilized nitrocellulose membrane
- A sample pad
- An absorption pad (also called absorbing pad or absorbent pad)
- A plastic backing

_i_-CHROMA iFOB Sample Collection Tube:

'Sample Collection Tube' is an essential component of _i_-CHROMA iFOB. A box containing 25 pre-filled sample collection tubes, is delivered separately from the test cartridge box. It is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

The sample collection tube is a specially designed plastic container. Each sample collection tube contains 1mL Detection Buffer. Apart from being the container for the detection buffer, the sample collection tube serves the following purposes:

i) Proper sampling of the fecal sample

ii) Thorough mixing of the fecal sample with the detection buffer for ensuring complete extraction of the fecal sample

iii) Application of precise quantity of the sample mixture into the 'Sample well' of the _i_-CHROMA iFOB test cartridge

'_i_-CHROMA iFOB Sample Collection Tube' contains 1 mL 'Detection Buffer'. Approximately 13 mg (±1.82 mg) of human fecal sample is actually delivered into the detection buffer in the '_i_-CHROMA iFOB Sample Collection Tube' following the sampling procedure described in the package insert of _i_-CHROMA iFOB test.

_i_-CHROMA Reader:

_i_-CHROMA Reader is a custom-configured, portable, desktop, fluorescence-scanning instrument for qualitative detection of fecal occult blood (FOB) in human fecal samples; duly mixed with the detection buffer and tested by _i_-CHROMA iFOB.

_i_-CHROMA Reader is intended to be used only in conjunction with _i_-CHROMA iFOB for _in vitro_ diagnostic purpose by laboratories and physician offices. _i_-CHROMA Reader measures 250 mm (L) x 185 mm (W) x 80 mm (H) in size and weighs 1.2 Kg.

The _i_-CHROMA iFOB test cartridge is loaded with the human fecal sample which has been duly mixed with the detection buffer in _i_-CHROMA iFOB Sample Collection Tube as per the standard test procedure recommended by Boditech Med Inc. This sample-

loaded test cartridge is inserted in to the cartridge holder of the *i*-CHROMA Reader for the purpose of being scanned.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes accumulated at the test line as well at the control line.

The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluorescent light. Intensity of the fluorescence is scanned and converted into an electric signal which correlates to the intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample.

The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration. The computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (positive or negative) manner.

Test Principle:

i-CHROMA iFOB is an immunoassay system based on antigen-antibody reaction and fluorescence technology.

When a human fecal sample is mixed with the detection buffer in the sample collection tube, the fluorochrome-labeled detector antibodies (anti-hemoglobin) in the detection buffer binds with hemoglobin in the fecal occult blood (FOB).

When the fecal sample mixture is loaded into the sample well on the test cartridge as per the recommended test procedure, it migrates through the nitrocellulose matrix of the test strip.

The fluorochrome-labeled detector antibody-analyte (FOB hemoglobin) complexes get captured on to the capture antibodies (anti-hemoglobin) which have been immobilized at the test line on the test strip.

As a result, the fluorochrome-labeled complexes of the detector antibody-analyte (FOB hemoglobin)-capture antibody get accumulated at the test line on test cartridge membrane.

Thus, more the hemoglobin in the human fecal sample, more the complexes that get accumulated at the test line on the test cartridge membrane.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of hemoglobin.

The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluorescent light. Intensity of the fluorescence is scanned and converted into an electric signal which is correlates to the intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample.

The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration.

The computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (positive or negative) manner based on an analytical cut-off of 100 ng/mL (hemoglobin in fecal sample mixed with detection buffer) which is equivalent to 8µg i.e. 0.008 mg hemoglobin per gram of stool.

i-CHROMA iFOB and *i*-CHROMA Reader are compatible only with each other.

Substantial Equivalence Information:

Predicate Device: OC Auto Micro FOB Test and Polymedco OC Auto Micro 80 Analyzer

Predicate K Number: K041408

Comparison with the Predicate Device:

Following table summarizes similarities and difference between the test device *i*-CHROMA iFOB and the predicate device OC Auto Micro FOB Test.

SIMILARITIES			
No.	**Comparison Parameter**	**Test Device (*i*-CHROMA iFOB with *i*-CHROMA Reader)**	**Predicate Device (OC Auto Micro FOB Test with Polymedco OC Auto Micro 80 Analyzer)**
1	Test Principle	Immunological test system using antigen-antibody reaction for detection of human hemoglobin in human fecal samples.	Immunological test system intended for qualitative detection of fecal occult blood in feces
2	Intended Use	Qualitative detection of fecal occult blood (FOB) in human fecal samples by laboratories and physician offices	Qualitative detection of fecal occult blood in feces by professional laboratories
3	Test Sample	Human fecal sample mixed with detection buffer in the sample collection tube	Feces in an extraction buffer
4	Test Cut-off	100 ng/mL (Human hemoglobin in human fecal sample mixed with detection buffer)	100 ng/mL (Human hemoglobin in feces processed in extraction buffer)
DIFFERENCES			
No.	**Comparison Parameter**	**Test Device (*i*-CHROMA iFOB with *i*-CHROMA Reader)**	**Predicate Device (OC Auto Micro FOB Test with Polymedco OC Auto Micro 80 Analyzer)**
1	Test Platform	Fluorescence immunoassay using lateral flow technology	Automated immunoassay using latex fixation
2	Test Time	10 minutes	5~10 minutes

3	Detection Mechanism	Involves scanning/measurement of intensity of fluorescence on the test cartridge membrane	Involves optical measurement of agglutination of latex particles

Standard/Guidance Document Referenced:

USFDA guidance document for industry and FDA staff:
'Review Criteria for Assessment of Qualitative Fecal Occult Blood In Vitro Diagnostic Devices' (Issue date: August 8, 2007)

Summary of Performance Testing (Bench):

- *i*-CHROMA iFOB showed **no prozone/hook effect up to** analyte concentration **2000 ng/mL**.
- *i*-CHROMA iFOB was found to be **equally sensitive to** 'Hemoglobin S' as the **abnormal hemoglobin** associated with sickle cell anemia.
- *i*-CHROMA iFOB showed **no significant cross-reactivity with** any of the eight **animal hemoglobin** (i.e. bovine, chicken, fish, horse/equine, goat, pig/swine, rabbit, and sheep origin) **and no significant interference from** any of the four **endogenous substances** (Ascorbic acid, Bilirubin, Albumin and Myoglobin).
- *i*-CHROMA iFOB **showed high degree of repeatability as well as** between-run, lot-to-lot, instrument-to-instrument and site-site **reproducibility.**
- **Analytical method comparison** study at three US sites performed on spiked human fecal samples **showed high degree of overall percent agreement** as well as **positive** percent agreement **and negative percent agreement between** test results obtained with ***i*-CHROMA iFOB** and the predicate method **OC Auto Micro FOB**.
- **Clinical testing study** at two Korean and one US site involving prospective testing of clinical human fecal samples showed:
  - **More than 96% positive and negative percent agreements** in test results when compared **with** the predicate method **OC Auto Micro FOB.**
  - **95-99.66% accuracy** in test results **with weak positive and weak negative samples.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 2, 2014

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c/o Sang Yoel Park, Ph.D., Senior Director QA & RA
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Chuncheon-si, Gang-won-do, 200-883
REPUBLIC OF KOREA

Re: k132167
Trade/Device Name: *i*-CHROMA iFOB with i-CHROMA Reader
i-CHROMA iFOB Controls
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult Blood Test
Regulatory Class: Class II
Product Code: OOX, JJX
Dated: April 23, 2014
Received: April 25, 2014

Dear Dr. Park:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132167

Device Name
i-CHROMA iFOB Controls

Indications for Use *(Describe)*
i-CHROMA iFOB Controls are external quality control reagents intended for monitoring and ensuring acceptable performance of i-CHROMA iFOB test system which is a qualitative in-vitro diagnostic test for detection of fecal occult blood having an analytical cut-off of 100 ng/mL which is equivalent to 8µg i.e. 0.008 mg hemoglobin per gram of stool.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Maria M. Chan -S

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132167

Device Name
i-CHROMA iFOB with i-CHROMA Reader

Indications for Use *(Describe)*

i-CHROMA iFOB in conjunction with i-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples.

i-CHROMA iFOB is an in vitro diagnostic test used by laboratories and physician offices for routine physical examination when gastrointestinal bleeding may be suspected.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

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Maria M. Chan -S